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EXAMINER	
HOPKINS, CHRISTINE D	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,202	BATCH, RICHARD M.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 11 September 2007. Claims 1-6, 8-17 and 19-23 are now pending. The Examiner acknowledges the amendments to claims 1 and 12.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claim 1, lines 14-15 recite "a processor…configured to automatically supply the medical device with at least one revised treatment guideline." The specification is not enabling for a processor configured to automatically supply the medical administration device with a treatment guideline, rather the specification teaches that a signal from the processor to the medical administration device indicates that the administration parameters entered into the administration device are appropriate for the medication and that institutional guidelines for the administration have been met [0102]. This recitation does not include a revised treatment guideline.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 8-17 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocionek et al. (U.S. Pub. No. 2002/0099273). Bocionek et al. (hereinafter Bocionek) disclose a medical information system which retains and processes information from various sources for use in clinical care delivery. Regarding claims 1, 3, 8-9 and 22, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the guideline ([0020], [0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline

representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. With further reference to claim 3, database **77** stores preestablished medical treatment guidelines [0020].

Regarding claims 2 and 4, a statistical distribution is provided by the analysis of the complied treatment parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds. Decision support functions **15** and **17** determine new or improved treatment solutions, thus adjusting acceptable values for the selected treatment parameter in the preestablished guidelines [0027]. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 5 and 6.

With respect to claim 10, the medical treatment data may include patient physiological data such as vital signs. Decision support functions derive conclusions based on the vital signs and available patient data and parameters to optimize settings and thresholds ([0026]-[0027]).

Regarding claim 11, Bocionek teaches a plurality of medication administration devices **81-87** for multiple patients, each associated with data acquired from a patient including patient identification, medication and operating parameters. A central processor **19**, **21** is configured to receive medical treatment data from the administration devices and a database **77** operatively connected to the processor stores preestablished medical treatment guidelines representing acceptable values for the

medical administration device operating parameters. Interface **90** interconnects medical devices within a patient's room to the central processor. The processor is further configured to compile a plurality of parameter values associated with a selected device operating parameter, analyzed the values and determine a medical treatment guideline based on the analysis representing acceptable values ([0016], [0017], [0028]).

Referring to claim 12, Bocionek teaches a method of communicating medical treatment data associated with medical treatments delivered to a plurality of patients, the treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each parameter; compiling from the treatment data a plurality of parameter values associated with a selected parameter; analyzing the complied treatment parameter values, determining an optimal treatment guideline based on the analysis and providing the optimized guideline to an infusion pump from a remote location ([0018], [0020], [0024], [0027]-[0030]). Regarding claim 13, a statistical distribution is provided by the analysis of the complied treatment parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds.

With reference to claim 14, database **77** stores preestablished medical treatment guidelines [0020]. Decision functions **15** and **17** compare compiled treatment parameter values such as from patient monitoring devices to the acceptable values for a treatment parameter retrieved from preestablished medical treatment guidelines in database **77** [0024]. The decision functions determine new and improved treatment solutions which are substituted for the existing solutions in database **77**, thus creating

an updated medical treatment guideline [0026], in accordance with claim 15. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 16 and 17.

Regarding claims 19-21, database **77** is dynamically updated to incorporate improved treatments and their associated medical outcome results [0020]. A processor connected to the database compiles from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyzes the values and determines a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022].

With respect to claim 23, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the guideline ([0020], [0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline

representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. Alarm function **29** generates an alarm based on vital signs collected from patient monitoring units. Decision support functions derive conclusions based on medical data and patient vital signs and parameters and optimize the alarm function settings and thresholds [0026].

Response to Arguments

6. Applicant's arguments filed 11 September 2007 with respect to the rejection of claims 1-6, 8-17 and 19-23 under 35 U.S.C. 102(b) citing Bocionek (U.S. Pub. No. 2002/0099273) have been fully considered and are not persuasive. Regarding claim 1, Applicant contends that Bocionek fails to disclose "a processor…configured to…automatically supply the medical device with at least one revised treatment guideline." However, this new limitation includes new matter, see rejection supra. Nonetheless, Applicant indicates that Bocionek instead discloses that the controlling of a device is different than automatically supplying a medical device with a revised treatment guideline. This argument is not persuasive. The claim languages requires a processor, and since the definition of such entails the manipulation of data or the performance of calculations, and the decision functions **15** and **17** generate prompts, medication selection guidance ("revised treatment guideline") and warnings [0022], it is held that the processor supplies the medical device with treatment guidelines regardless of the fact that a device controller, used in conjunction with the decision functions as

pointed out by Applicant, may operate to physically or mechanically control the medical administration device. Furthermore, while Applicant contends that "the optimal drug dosage to be applied by [an] infusion pump" in Bocionek clearly shows that the device of Bocionek is receiving an instruction and not a guideline, it is submitted that the decision support functions determine optimal drug dosage to be applied by the pump based on medical data, deeming such "instruction" as interpreted by Applicant, as a "treatment guideline."

Regarding claim 11, Applicant contends that the modules and functions in Bocionek update patient records rather than the recited medical devices, and the updating does not involve treatment guidelines. However, this argument is not persuasive. The modules and functions of Bocionek adaptively update and improve the analysis system based on stored data including treatment outcome data, specifically taught at paragraph [0030] which are utilized to provide treatment from a medical device. The modules and functions also reflect a determined prescription and proposed treatment ("treatment guidelines").

Regarding claim 12, Applicant contends that the "medical parameters" and "treatment outcome data" as taught by Bocionek are different from the "medical treatment guideline" recited in claim 12. Thus, Applicant concludes that the medical parameters and treatment outcome data of Bocionek are merely data rather than "a guideline representing acceptable values for the selected treatment parameter. However, this argument is not persuasive because the system of Bocionek establishes guideline data in the analysis system whereby the treatment guidelines are updated and

improved based on the analysis of medical parameters and treatment outcome data as indicated at paragraph [0030].

Regarding claim 23, Applicant contends that the alarm of claim 23 is activated "when a medical treatment guideline having parameters outside of the appropriate parameters is input into [a] medication device," whereas the alarm as taught by Bocionek is activated "based on vital signals collected from patient monitoring devices." However, this argument is not persuasive. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The alarm, as taught by Bocionek, is fully capable of generating an alert based on treatment parameters as it is functional in the teachings to be signaled based on any parameter relative to a patient's data which falls outside a specific, pre-established threshold [0026]. In view of the foregoing, the rejection of claims 1-6, 8-17 and 19-23 under 35 U.S.C. 102(b) citing Bocionek (U.S. Pub. No. 2002/0099273) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
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